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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

Address to:
Commissioner for Patents
Box RCE
Washington, DC 20231

Application Number	08/833,838
Filing Date	April 10, 1997
First Named Inventor	Bruce D. Gaynor
Art Unit	1644
Examiner Name	G.R. Ewoldt, Ph.D.
Attorney Docket Number	96700/451

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114

a. ☐ Previously submitted
   i. ☐ Consider the amendment(s)/reply under 37 CFR 1.116 previously filed on _____
   (Any unentered amendment(s) referred to above will be entered).
   ii. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
   iii. ☐ Other _____

b. ☒ Enclosed
   i. ☒ Amendment/Reply
   ii. ☐ Affidavit(s)/Declaration(s)
   iii. ☐ Information Disclosure Statement (IDS)
   iv. ☒ Other cover letter

2. Miscellaneous

a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

b. ☐ Other _____

3. Fees — The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

a. ☒ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. 01-1785
   i. ☐ RCE fee required under 37 CFR 1.17(e)
   ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)
   iii. ☒ Other Any required fee to preserve the pendency that is not already paid.

b. ☒ Check in the amount of $830.00 enclosed

c. ☐ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Name (Print/Type)	Elie H. Gendloff	*Registration No. (Attorney/Agent)*	44,704
Signature		*Date*	December 6, 2001

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner For Patents, Box RCE, Washington, DC 20231, or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Name (Print/Type)	Elie H. Gendloff		
Signature		*Date*	December 6, 2001

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Dkt. No. 96700/451

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Bruce D. Gaynor et al.
Serial No.	:	08/833,838
Filed	:	April 10, 1997
For	:	PEPTIDES FOR THE TREATMENT AND DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS
Examiner	:	G.R. Ewoldt, Ph.D.
Group Art Unit	:	1644

"Express Mail" mailing label No. EL777785065US
Date of Deposit: December 6, 2001
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202.
Name: Elie H. Gendloff
Signature:

RESPONSE ACCOMPANYING REQUEST FOR CONTINUING EXAMINATION FILING UNDER 37 C.F.R. 1.114

Commissioner for Patents
Washington, D.C. 20231

Sir:

This Response accompanies a Request for Continuing Examination (RCE) in the above case. Also enclosed is a check for $830.00, which covers the RCE fee and a three month extension of time fee. Applicants hereby request a three month extension of time. A Notice of Appeal was filed on July 9, 2001. With the three month extension of time, this response is due on December 9, 2001, and is therefore timely filed.

Remarks

Claims 54 - 74 are pending in this case. Claims 55 - 62 are objected to, and claims 54 and 63 - 74 stand rejected under 35 U.S.C. 102(a) and/or 35 U.S.C. 103(a).

Rejection under 35 U.S.C. 102(a)

Claims 45, 49, 51, and 53 stand rejected under 35 U.S.C. 102(a) as being

anticipated by Spatz et al., 1997, METHODS: A Companion to Methods in Enzymology 11:70-78. That rejection (and the rejection under 35 U.S.C. 103(a)) was first entered in the Office Action of June 20, 2000. The rejection states:

> Spatz et al. teach a method for treating renal failure (glomerulonephritis) mediated by αds-DNA antibodies comprising the administration of the αds-DNA antibody-binding peptide, (D/E)W(D/E)Y(G/S) (SEQ ID NO:4) and other peptides to a subject, (see particularly page 70, column 2, paragraph 1 and page 73, column 1, last paragraph - column 2, first paragraph).

However, upon evaluation of Spatz et al., applicants could find no disclosure that the claimed methods were performed. Additionally, applicants could not find an enabling disclosure of the claimed methods in Spatz et al. Page 70, column 2 has no mention of αds-DNA antibody-binding peptides at all, and only disclose activities related to understanding the regulation and pathogenic potential of αds-DNA antibodies. The cited paragraph on page 73 only discusses the identification of peptides (including SEQ ID NO:4) that compete for antibody binding sites with dsDNA. The second to the last sentence in that paragraph also states, "... peptides may be valuable therapeutic reagents in SLE, used either to block renal sequestration of anti-dsDNA antibody or to tolerize pathogenic B cells. Their efficacy as therapeutic reagents can be tested in transgenic models of disease." The only other reference to the peptides in Spatz et al. is in the last paragraph of the paper, on page 76. The relevant part of that paragraph states, "... administration of peptide to transgenic mice will identify those peptides that block kidney deposition of the anti-dsDNA antibody." Applicants could find no other reference relating to the claimed invention in Spatz et al.

The above quotes from Spatz et al. clearly indicate that the claimed methods had not been performed. They are merely a suggestion of a way to proceed to determine whether the claimed methods, or methods using other peptides, would work. There is

no indication that this suggestion is an enabling disclosure, since the disclosure provides doubt that the claimed methods would even work ("... peptides may be valuable therapeutic agents ..."; "... administration of peptide ... will identify those peptides that block kidney deposition ..."). Since Spatz et al. does not disclose an enabling disclosure by providing a method that anticipates all elements of the claims such that the skilled artisan would understand has a reasonable likelihood of success, that reference does not anticipate the methods of the rejected claims. Applicants therefore respectfully request reconsideration and withdrawal of the rejection of claims 45, 49, 51, and 53 under 35 U.S.C. 102(a) as being anticipated by Spatz et al.

Rejection under 35 U.S.C. 103(a)

Claims 45 - 46 and 51 - 52 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Spatz et al. It is asserted that Spatz et al. anticipates the claims with respect to the L isomers and that the D isomers are close enough to be obvious variants to the L isomers.

As discussed above, applicants assert that Spatz et al. does not anticipate any claims because the reference does not provide an enabling disclosure of the claimed methods. Applicants also assert that Spatz et al. does not make any of the claims obvious, since the reference provides doubt that the claimed methods would work. This is reflected in the statements " ... peptides may be valuable therapeutic reagents ...", and " ... administration of peptide ... will identify those peptides that block kidney deposition ...". These statements indicate that the authors of Spatz et al. do not believe that the identified peptides, (D/E)W(D/E)Y(G/S) and (D/E)G(D/E)WP, or any peptide at all, would necessarily be useful for treating glomerulonephritis as claimed.

The skilled artisan, without the benefit of the instant application, would also have doubts that the claimed method would work. For example, the peptides in the claimed

methods would not necessarily be understood to compete for anti-dsDNA antibody binding sites well enough to prevent binding to the kidneys. Additionally, even if the peptides bind to the anti-dsDNA antibodies, the peptide - anti-dsDNA antibody complex could still cause glomerulonephritis. Spatz et al. does nothing to erase those doubts. Indeed, Spatz et al. also expresses doubt that the claimed methods would necessarily work, both in general and by using the particular peptides that are recited in the claims.

At most, Spatz et al. makes the methods in the rejected claims obvious to try, without providing the skilled artisan the required assurance that the claimed methods would have a reasonable likelihood of success. *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). As is well known, establishing that a claimed method is obvious to try is not sufficient to establish a rejection under 35 U.S.C. 103(a). *In re O'Farrell*, 7 USPQ2d 1673, 1680 - 1 (Fed. Cir. 1988). The fact that the method that was suggested in Spatz et al. did work, as disclosed in the present specification, is irrelevant to an analysis of obviousness, since the applicants' disclosure cannot provide the reasonable expectation of success required to sustain an obviousness rejection. *Vaeck*, at 1442. Hindsight is impermissible in evaluating obviousness. See, e.g., MPEP 2145 X.A.

Since Spatz et al. does not provide a disclosure of the invention whereby the methods of the rejected claims could be practiced with a reasonable expectation of success, applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. 103(a).

Conclusion

In light of the above discussion, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. 102(a) and 35 U.S.C. 103(a) and passage of the claims to allowance. Should there be any additional matters that prevent allowance of the claim, the Examiner is urged to contact the undersigned attorney.

No fee, other than the enclosed $830 for the RCE filing and a three month extension or time, is deemed necessary in connection with this filing. If any additional fee is required to preserve the pendency of the subject application, authorization is hereby given to charge any such additional fee to Deposit Account No. 01-1785.

Respectfully submitted,

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Dated: New York, New York
December 6, 2001

By: _____
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